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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/014,877 | 12/11/2001 | Matthew L. Albert | 600-1-291 CON | 4555 |

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EXAMINER

NICKOL, GARY B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,877

Applicant(s)

ALBERT ET AL.

Examiner

Gary B. Nickol Ph.D.

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 and 55-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-27, 31-48, 50 and 57-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30, 49, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Re: Albert *et al.*

Date of priority: 02-20-1998

Request for Continued Examination

The request filed on July 25, 2005 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/014877 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 1-50, and 55-61 are pending.

Claims 1-27, 31-48, 50, 57-61 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 28-30, 49, and 55-56 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejection Maintained:

Claims 28-30, 49, and 55-56 remain rejected under 35 U.S.C. 102(b) as being anticipated by ENGLEMAN *et al.* (WO 94/02156, February 3, 1994) for the reasons of record and for the reasons set forth below.

Applicants argue (Response, page 10) that Engleman *et al.* do not teach the methods of the present invention as currently claimed. Applicants note, for example, that newly amended Claim 28 includes the additional step of:

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“...wherein the apoptotic cell may be shown to be apoptotic by a procedure selected from the group consisting of Annexin V staining, propidium iodide staining, DNA laddering, and staining with dUTP and terminal transferase (TUNEL staining),..”.

With regards to the above amendment, applicant's arguments have been carefully considered but are not deemed persuasive. While the prior art does not specifically teach the above recited procedures, said procedures are not *limited* to the method of Claim 28. The claim only recites that the apoptotic cells “may” be shown to be apoptotic. Hence, as claimed, the procedures are merely optional, not required.

Applicant further argue (Response, top of page 11) that while Engleman *et al.* taught the use of irradiating cells, their “intent” was not to induce apoptosis. Applicants argue that the examples on pages 29-34 of the reference (and in particular, sections 7 and 7.2) do not specifically teach irradiation of the antigens, in particular KLH, SWM, and HIV gag peptide antigens prior to exposure to the dendritic cells for T cell activation. Moreover, applicants argue that Engleman *et al.* do not transfer these antigens to dendritic cells by way of an apoptotic cell. Applicants argue that, “The antigens of Engleman *et al.* are presented to the dendritic cell in the absence of an apoptotic cell.” These arguments have been carefully considered but are not found persuasive. First, with regards to Engleman's “intent”, arguments that the alleged anticipatory prior art is not recognized as solving the problem solved by the claimed invention, are not germane to a rejection under section 102. *Twin Disc, Inc. v. United States*, 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting *In re Self*, 671 F.2d 1344, 213 USPQ 1, 7 (CCPA 1982)). >See also *State Contracting & Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1068, 68 USPQ2d 1481, 1488 (Fed. Cir.2003). The question of whether a reference is analogous art is not relevant to

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whether that reference anticipates the claims. A reference may be directed to an entirely different problem than the one addressed by the inventor, or may be from an entirely different field of endeavor than that of the claimed invention, yet the reference is still anticipatory if it explicitly or inherently discloses every limitation recited in the claims. (See MPEP 2131.05). Furthermore, in arguing Engleman's intentions, applicants have only referred to a portion of Engleman's teachings. However, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In *re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Secondly, with regards to the argument that the reference does not specifically teach the "irradiation of the antigen" prior to exposure to the dendritic cells for T cell activation, it is noted that the claims do not require such a limitation. Thirdly, in contrast to the argument that "The antigens of Engleman *et al.* are presented to the dendritic cell in the absence of an apoptotic cell," Engleman *et al.* specifically teach (page 20, lines 8-10) that "antigens may be used as purified naturally occurring whole polypeptides, purified recombinant whole polypeptides, whole organisms or cells in "viable or dead forms". Further, as set forth previously (Action, mailed 02-16-2005), Engleman *et al.* clearly teach the exposure of dendritic cells with tumor cells which have been irradiated (page 19).

Applicants have further presented a declaration under 37 CFR 1.132 by the inventor Matthew Albert which attests that the use of any irradiation, gamma or ultraviolet, may result in either death of the cell by necrosis or in apoptosis wherein the outcome is dependent on the doses as well as the time of exposure. Applicants argue that the specification clearly points out the particular doses and times of exposure. This argument has been considered but is not found persuasive because arguments that rely on particular distinguishing features are not persuasive

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when those features are not recited in the claims. Narrow limitation contained in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. See *In re Philips Industries, Inc. v. State Stove & Mfg. Co.*, 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992). Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims. Further, since the claims do not require the standard procedures used to detect apoptosis as recited in Claim 28 (i.e., Annexin V staining, propidium iodide staining, etc.), the claims only read on contacting dendritic cells with an “apoptotic cell”. The specification defines an “apoptotic cell” (page 24, line 20) as any cell expressing a native or foreign antigen undergoing apoptosis due to *any* condition, including those which usually are associated with causing “necrosis”. (Note: Here, the specification actually recites the word “neurosis”, but since neurosis is usually a word associated with a psychological or behavioral disorder, it was assumed that the inventor’s meant “necrosis”). Thus, when compared to the teachings of the prior art’s “dead cell” and irradiated cells, the broad definition of an apoptotic cell is ambiguous, at best, because it would appear that the method would comprise necrotic cells too because the claims do not unequivocally distinguish necrotic cells from apoptotic cells.

Applicants further reiterate (Response, page 14) their arguments that the prior art reference is non-enabling. This argument has been considered but is not found persuasive for the

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reasons of record in the Action mailed 02-16-2005. Thus, applicant's arguments have not been found persuasive, and the rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN



GARY B. NICKOL, PH.D.
PRIMARY EXAMINER